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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,223	04/20/2000	Gregory B. Williams	MN-9050	5050

7590

12/14/2001

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EXAMINER

GUTTMAN, HARRY J

ART UNIT

PAPER NUMBER

1651

8

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/553,223

Applicant(s)

WILLIAMS ET AL.

Examiner

Harry J Guttman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims and Application***

Claims 22-36 are pending.

The Response with amendment filed October 5, 2001 has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

The documents listed in the PTO-1449 submitted July 23, 2001 are not found. The Office has produced the US and foreign patents listed as A01 through A82 and B01 through B04. Louis Cullman was asked to FAX copies of documents C01 through C17, but these documents have not been received. As such, documents C01 through C17 have not been considered.

### ***Claim Rejections - 35 USC § 112***

Amended claims 22-36 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 22 line 1 now recites "identify". This should be "identity".

Amended claim 22 now recites step (i) to simultaneously determine a microorganism's ID and susceptibility to an antimicrobial agent. It is unclear how

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simultaneous is to be interpreted. The dictionary definition for simultaneous is that which occurs "exactly coincident". However, the suspensions are analyzed (according to step (h)) independently, individually and on two different samples. Since it does not appear to be possible to do these analyses "exactly coincident", the use of the word simultaneous is incorrect. Perhaps "in parallel" would be a more appropriate phrase. Correction is required.

Amended Claim 22 is now rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. It is noted that claim 22 has been amended to read explicitly on identifying a single microorganism; prior to amendment the claim read on distinguishing between two clinically significant microorganisms. The identification of a microorganism requires a battery of tests, not one or two tests, as minimally required by the claim. These tests are currently omitted and must be included explicitly. Correction is required.

### ***Claim Rejections - 35 USC § 103***

Amended claims 22-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (US 5164301) in view of Clark et al. (WO 98/53301) and Fisher Biotechnology Catalog (1995, page 114 and 116).

The Response argues that Thompson et al. do not teach that both turbidity and fluorescence are performed simultaneously to perform different assays.

Thompson et al. (US 5164301) teach antimicrobial susceptibility testing using microtiter plates (column 11 lines 60-66) at 30-35°C (column 8 line 49). Turbidity was measured simultaneously on a parallel sample without dye (column 12 lines 2-5). The MIC of penicillin was measured at 3 hours after initial incubation (column 12 lines 14-16). They also disclose using fluorescent agents for microbial identification within seven hours of initial incubation (column 12 lines 26-50). They discuss automating the process and interfacing with a computer (column 13 lines 19-37).

Thompson et al. do not explicitly disclose the use of a modified microtiter plate. Thompson et al. do not perhaps explicitly state that the antimicrobial susceptibility testing and the microbial ID are to be performed in parallel. Thompson et al. do not explicitly teach the manual/automation steps as claimed.

Clark et al. (WO 98/53301) teach an apparatus and method for performing ID and AST on the same multi-well plate during the same measurement period in parallel. The method uses absorption, turbidity and fluorescent measurements (abstract, summary of the invention, page 27 lines 10-22 and page 29 lines 25-30). The range of times for incubation and testing ranges from 2 minutes to 24 hours (page 36 lines 7-26).

The Fisher Biotechnology Catalog (1995, page 114 and 116) sold microtiter plates that have clear bottoms and walls that are black, or white for the explicit use in fluorescence assays. It is noted that one of ordinary skill in the art at the time the invention was made would recognize that plates that have the optical quality for fluorescence measurements also have the optical quality for absorbance/turbidity

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measurements since the optical requirements for fluorescence are much more demanding; this concept is old and well known in the art.

One of ordinary skill in the art would have been motivated to perform the AST and ID tests in parallel because it was well known in the art to do so, as demonstrated by Clark et al. Also, the parallel measurements were clearly the intended goal of Thompson et al., especially given (1) Thompson et al.'s statement referring to a single test for both AST and ID - "the present invention provides a rapid microbial identification and susceptibility test" (emphasis added - column 13 lines 10-13) and (2) there are multiple points in figures 11-14, clearly indicating data acquisition was capable and intended to be performed on both AST and ID, in parallel. Further, since the ability and intention to perform the tests in parallel is clear, combining them (such as described in Figure 1 of the application) is simply a matter of routine optimization to increase efficiency in the measurements. Finally, it is noted that automation of a manual activity for the same result is not sufficient to distinguish over the prior art (MPEP 2144.04.III page 2100-131 August 2001).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed October 5, 2001 have been fully considered but they are not found persuasive for the reasons of record and for the additional reasons above.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Harry J. Guttman, Ph.D. at telephone number (703) 305-0159. The examiner can normally be reached during the hours of 07:30 to 16:00 Eastern Time, Mon.-Thurs. If attempts to reach the examiner by telephone are unsuccessful, a message may be left on the voice mail. The fax number for Art Unit 1651 is (703) 308-4242 or 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. My supervisor, Michael Wityshyn, may be contacted at (703) 308-4743.

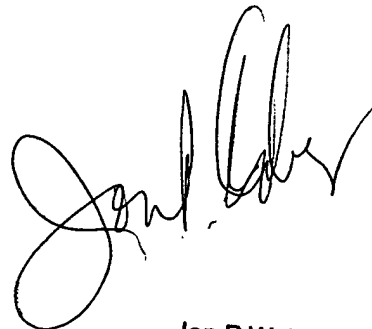
All internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified or exchanged unless there is of record an express waiver of the confidentiality requirements of 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published in the Patent and Trademark Office Official Gazette on 25 February 1997 at 1195 OG 89.

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H.J.G. 13 December 2001

A handwritten signature in black ink, appearing to read 'Harry J. Guttman', with a stylized, flowing script.

Harry J. Guttman, Ph.D.  
Examiner, 1651  
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A handwritten signature in black ink, appearing to read 'Jon P. Weber', with a stylized, flowing script.

Jon P. Weber, Ph.D.  
Primary Examiner